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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,933	11/21/2001	Xuemei Cao	PC11050A	1576
25533	7590	01/22/2007	EXAMINER	
PHARMACIA & UPJOHN			LUCAS, ZACHARIAH	
7000 Portage Road			ART UNIT	
KZO-300-104			PAPER NUMBER	
KALAMAZOO, MI 49001			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/989,933	CAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35, 37, 42-45, 48-53, 56-59, 69-72 and 75-88 is/are pending in the application.
- 4a) Of the above claim(s) 42-45, 48-53, 56-59, 69-72, 75 and 76 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 and 37 is/are allowed.
- 6) ☒ Claim(s) 77-84, 87 and 88 is/are rejected.
- 7) ☒ Claim(s) 85 and 86 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 35, 37, 42-45, 48-53, 56-59, 69-72, and 75-88 are pending in the application.
2. Claims 42-45, 48-53, 56-59, 69-72, 75, and 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 11, 2006.
3. Claims 35, 37, and 77-88 are under consideration.

#### *Specification*

4. **(Prior Objection- Withdrawn)** The amendments filed March 1, 2005 and February 22, 2006 were objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. In view of the amendments to the application, the objection is withdrawn.
5. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: the most recent amendment to the specification (submitted on February 2, 2006 does not comply with the requirements of 37 CFR 1.121. In view of the amendments and arguments presented, the objection is withdrawn.
6. **(New Objection- Necessitated by Amendment)** The disclosure is objected to because of the following informalities: the application indicates on (e.g.) page 1 that U.S. application 08/107908 has indicated that the BVDV N<sup>pro</sup> protein and coding sequence are not required for viral replication. However, this application does not appear to provide such teachings. It is

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suggested that the application be amended to indicate that the art (generally) have provided such teachings, and not the indicated U.S. application.

Appropriate correction is required.

### ***Claim Objections***

7. **(Prior Objection- Withdrawn)** Claims 30 and 31 were objected to because of the following informalities. In view of the cancellation of these claims, the rejection is withdrawn.

8. **(New Objection)** Claims 85 and 86 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. **(Prior Rejection- Maintained)** Claims 39, 40, 63, and 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on cells, and not isolated cells, including human cells. In view of the amendments to the claims, the rejection is withdrawn from cancelled claims 39, 40, 63, and 64; but is maintained against new claim 84.

### ***Claim Rejections - 35 USC § 112***

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11. **(Prior Rejection- Withdrawn)** Claim 31, 60-68, 73, and 74 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 30-34, 36, 38-41, 46, 47, 54, 55, 60-68, 73, 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking adequate support for the genus of attenuated bovine viral diarrhea viruses, the viruses comprising a mutated N<sup>pro</sup> coding sequence comprising an intact 5' region of at least 36 (or 310) base pairs, wherein the mutated N<sup>pro</sup> coding sequence encodes an inactive N<sup>pro</sup> protein. In view of the cancellation of the prior claims, and as the combination of the assay and the provided working example are found sufficient to demonstrate possession of the genus of new claims 77, 78, 81, and 82, the rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claims 30-34, 36 38-41, 46, 47, 54, and 55 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an attenuated BVDV that has about 310 base pairs of the Npro gene intact, does not reasonably provide enablement for the scope of mutations to Npro claimed or an intact Npro. In view of the amendments to the claims, the rejection is withdrawn.

#### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **(Prior Rejection- Maintained)** Claims 30, 33, 36, 38-41, 46, 47, 54 and 55 were rejected under 35 U.S.C. 103(a) as being unpatentable over Behrens et al. (Journal of Virology. 1998; 72 (3): 2364-2372). The previously rejected claims have been cancelled. The rejection is therefore withdrawn from the prior claims, but is extended to new claims 77-84, 87, and 88.

New claims 77, 79-81, 83-84, 87, and 88 require only the presence of a deletion comprising 196 3' bases (i.e. at least 196 bases) in the Npro sequence. Such a limitation is met by the reference, which teaches replication competent viral sequences comprising only the 5' 129 (of 508) bases of the Npro gene. Further, although the reference incorporates these deletions into only subgenomic particles, the teachings of the reference indicate that this sequence (fused to the ubiquitin gene) would allow for replication if incorporated into the complete viral genome. Thus, it would have been obvious to those of ordinary skill in the art to have used the deletion mutant Npro gene disclosed in the reference as a functional equivalent for the native Npro gene found in the BVDV genome.

New claims 78 and 82 read on a BVDV genome (or virus comprising such) having at least 308 base pairs in the 5' sequence of a mutated Npro gene. Such viruses are not disclosed by the reference. However, as indicated above, the reference indicates that only the 126 5' bases would be required for a replication competent mutant BVDV replicon. Thus, it would have been obvious to those of ordinary skill in the art that additional bases in the 5' sequence could also be included so long as the required 126 bases are present. Thus, claims 78 and 82 also read on obvious variations of the virus particles and nucleic acid sequences taught by the reference.

In addition to the amendments to the claims, the Applicant also argues that the compositions disclosed in the reference would not qualify as veterinarily-acceptable carriers. This argument is not found persuasive. While the application does include descriptions of what might be considered to be such a carrier, the application contains no definition that excludes virus particles found in a culture medium. Moreover, as it would have been obvious to have produced the mutated viruses as indicated above, it would also have been obvious to those of ordinary skill in the art to isolate such viruses for reinfection into additional cells. The Applicant's arguments in traversal of the rejection as it applies to the new claims are not found persuasive. The rejection is therefore maintained over the indicated new claims for the reasons above, and the reasons of record.

#### ***Conclusion***

16. Claims 35 and 37 appear allowable over the art.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

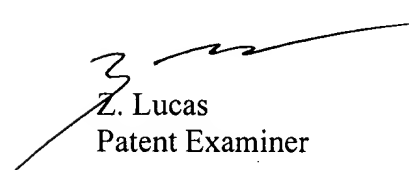
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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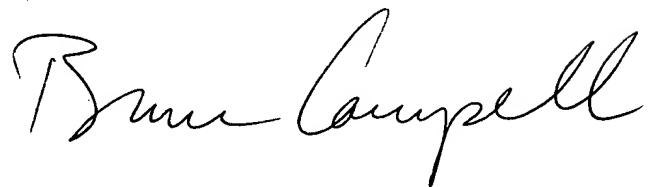
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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